federal register

THURSDAY, AUGUST 4, 1977
PART III

CONSUMER PRODUCT SAFETY COMMISSION

■

IDENTIFICATION OF CERTAIN TOYS AND OTHER ARTICLES PRESENTING POTENTIAL PUNCTURE OR LACERATION INJURY HAZARDS DUE TO SHARP POINTS

Technical Requirements

CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Part 1500]

IDENTIFICATION OF CERTAIN TOYS AND OTHER ARTICLES PRESENTING POTENTIAL PUNCTURE OR LACERATION INJURY HAZARDS DUE TO SHARP POINTS

Proposed Technical Requirements

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed Regulation.

SUMMARY: The Commission is proposing a regulation that would establish technical requirements for toys and other articles intended for use by children under 8 years of age. These requirements would identify sharp points on such children's articles that could injure children. If the Commission identifies sharp points on particular children's articles that present an unreasonable risk of injury to children under 8 years of age, it will initiate rulemaking proceedings to ban those articles.

DATES: Comments must be received on or before September 6, 1977. The proposed effective date woud be 365 days after publication of final requirements.

ADDRESS: Send comments to the Office of the Secretary, Consumer Product Safety Commission, 1111 18th Street NW., Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT:

Elaine Besson, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207 (301–492–6550).

SUPPLEMENTARY INFORMATION: On January 7, 1975, the Consumer Product Safety Commission, pursuant to section 2(f)(1)(D) of the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261(f)(1)(D), proposed regulations to ban toys intended for children under 8 years of age[1] that present an unreasonable risk of personal injury from puncture or laceration hazards due to sharp points (40 FR 1491). The proposed regulations also set forth test criteria for determining whether toys intended for children under 8 years of age present these hazards.

At the Commission meeting of April 7, 1977, the Commission voted to withdraw its proposed regulations and to repropose the sharp point test criteria, with certain changes, as a technical requirements regulation.

The effect of the technical requirements regulation proposed in this document, if issued in final form, would be to identify toys containing sharp points that the Commission preliminarily believes are hazardous to children under 8 years of age. Because such toys may not always present a mechanical hazard under the FHSA (section 2(s), 15 U.S.C. 1261(s)), the Commission is not proposing a regulation that would automatically classify such toys as banned hazardous substances. Instead, the Commission will regulate such toys on a product-by-product basis whenever the test procedures identify them as presenting sharp points and the Commission believes that they present a mechanical hazard as defined in the FHSA.

The Commission's reasons for its proposal of this product-by-product regulatory approach for toys with points and the manner in which the Commission will use this approach are discussed below.

Rationale For Reproposal

The Commission has decided to withdraw the January 7, 1975 proposed regulation and to repropose the sharp point test criteria, with certain changes, as a technical requirements regulation for the following reasons:

1. The proposed banning regulation of January 7, 1975 and the technical requirements regulation proposed below include in their scope all products intended for children within an age span ranging from 0 to 8 years. However, the Commission believes that it would be unwise to attempt to apply a single sharp-point test criterion in a self-executing banning regulation to the numerous products which make up the play environment of children between the ages of 0 and 8 years. Sharp point tests on toys conducted by the Commission staff showed that some points which were classified sharp by the test instrument and were accessible by the criteria of the proposed regulations do not constitute an unreasonable risk of injury.

The Commission therefore believes that factors other than the tip geometry of a point, such as construction material of the point and its location on a toy and the intended use and foreseeable misuse of the toy, should be considered when making a determination that a toy presents a mechanical hazard under the FHSA (section 2(s), 15 U.S.C. 1261(s)).

2. Staff analyses of the Commission's injury data associated with products intended for children indicate that injuries to young children are predominantly lacerations, punctures and avulsions. However, many of these injuries appear to occur as a result of some form of violent activity such as swinging or throwing the product, or running and subsequently falling on it. This type of activity and the resultant potential risk of injury associated with children's products was never intended to be addressed by the proposed banning regulations of January 7, 1975. Rather, that proposal was aimed at the casual handling of toys, which includes the range of activity associated with unpacking, handling, operating, and playing with toys, including foreseeable misuse and types of play not intended by the manufacturer.

For the reasons discussed above, the Commission is proposing in the regulation below certain technical requirements for manufacturers to follow in designing and manufacturing toys without sharp points.

Toys that do not comply with the technical requirements will be reviewed by the Commission and its staff on a product-by-product basis for further regulatory action. Under this approach, toys not meeting the technical requirements would not be classified as banned hazardous substances under the FHSA until they are the subject of a completed proceeding under section 2(f)(1)(D) of the FHSA (15 U.S.C. 1261). In contrast, under the approach that was proposed in January 1975, toys not meeting the sharp point test criteria would have been automatically banned.

The Commission believes that consumers, state and local governments, and other interested persons should be given an opportunity to comment on the technical requirements regulation followed by a product-by-product banning approach before the Commission adopts it.

Background

In response to the Commission's January 1975 proposed regulations on sharp points, comments were received from 29 individual toy manufacturers or importers, seven trade associations, two retailers, two consumers, one consumer group, one nonprofit organization, and one unidentifiable commentor.

The Commission's responses and conclusions to the major issues raised in the comments that are pertinent to the proposal are discussed below.

1. *Injury data.* In response to comments that injuries reflected in the Commission's National Electronic Injury Surveillance System (NEISS) are not caused by toys themselves but are merely associated with the toy, the Commission believes some commentors may have misunderstood how the Commission uses NEISS surveillance data.

The Commission points out that NEISS surveillance data are primarily an indicator of need and not a justification for regulation because NEISS does not distinguish between product-caused and product-related injuries and does not identify whether an injury resulted from the normal use or the reasonably foreseeable misuse of a product. Such information is obtained through in-depth investigations that are performed by the Commission. However, NEISS surveillance data provide information on the type and severity of injuries and the ages of those being injured. Therefore, NEISS data are only one factor the Commission uses in making its findings of an unreasonable risk of injury pursuant to the FHSA. In addition, the Commission offers the following explanation of how NEISS surveillance data are applicable to the regulation proposed below.

A review of NEISS injury data indicates that a substantial number of

[1] The Commission intends that the scope of this technical requirements regulation will include other articls intended for use by children under 8 years of age as well as toys. However in an effort to simplify reading the preamble, the term toy(s) hereafter will be used inclusively for both toys and other articles intended for use by children.

children under 8 years of age are receiving laceration and puncture injuries from toy-related accidents. In calendar year 1976 an estimated 43,300 children under 8 years of age were treated in hospital emergency rooms for such injuries.

In order to determine the extent to which lacerations and punctures are occurring from toys intended for children under 8 years of age, the Commission staff divided toys into the following three categories.

a. Toys primarily intended for use by children under the age of 8 years.

b. Toys primarily intended for use by children 8 years to 14 years of age.

c. Toys intended for use by children in both age groups.

Of the estimated 43,300 injuries treated in 1976, an estimated 9,000 were associated with products intended specifically for use by children under 8 years of age. An additional 30,800 injuries were associated with products intended for use by children in both the under 8 year and in the 8-to-14 year age groups.

In addition based on NEISS estimates, laceration and puncture injuries accounted for over half (approximately 53 percent) of all toy related injuries to children under 8 years of age.

The Commission points out that injuries of the type addressed by the regulation being proposed are serious enough to require emergency room treatment as shown by the fact that NEISS surveillance data are obtained from reports of injuries that are treated in hospital emergency rooms. The Commission believes that a purchaser of toys for children under 8 years of age does not expect such articles to cause laceration or puncture injuries to the children using them. The Commission therefore finds toys that can puncture or lacerate skin and cause bleeding, during normal use or reasonably foreseeable misuse, constitute an unreasonable risk of injury.

The Commission recognizes some commentors were concerned that reports of punctures accounted for a small percentage of the reported toy-related injuries reflected in the January 7, 1975 proposal. The Commission points out that many puncture wounds, however, are often reported in NEISS as foreign body lodgments or lacerations. Further, the proposed regulation below is directed also to the reduction of laceration injuries.

The Commission finds that while many toy-related puncture and laceration injuries may be scratches and finger prickings causing minor bleeding, there are a sufficient number of injuries which are more severe. Such injuries warrant the adoption of reasonable regulations to reduce or eliminate their occurrence.

The Commission emphasizes that the proposed technical requirements are intended to set a standard of safety to reduce the risks of injury not only for the products currently available to young children but also fort he new and redesigned products for which there is no hazard experience data available to the Commission. The Commission estimates that between 3,000 to 5,000 new children's products are introduced into the marketplace each year. It is anticipated therefore that the technical requirements proposed below will reduce the occurrence of puncture and laceration injuries associated with the new products that will be available for children.

The injury reports and the Commission staff's analysis of injuries related to sharp points on toys may be seen in the Office of the Secretary, Consumer Product Safety Commission, 1111 18th Street, NW., Washington, D.C., during working hours Monday through Friday

2. *Sharp point test criteria.*—a. *Sharp point tester.* The proposed January, 1975 regulations prescribed a sharp point tester developed for the Commission by the National Bureau of Standards (NBS). The sharp point tester was designed to distinguish, on the basis of sharpness, between the sharp and dull points that children can contact during the casual handling of toys. Casual handling includes the range of activity associated with unpacking, handling, operating, and playing with toys, including foreseeable misuse andother types of play not intended by the manufacturer. While foreseeable misuse certainly includes the throwing or swinging of toys at high velocities, under those conditions, the degree of injury that results is more a function of velocity than the detailed geometry of the point. Thus, this regulation stops short of considering the highest forces that may be involved in children's play. NBS data indicated that a force of 16.5 pounds was reasonably representative of the forces commonly involved in the handling of toys by children under 8.

In determining the sharpness of various points to develop the sharp point tester, NBS considered data from three sources:

i. Subjective evaluation by 50 adult males and 50 adult females (nonphysicians) of the sharpness of a set of manufactured conical metal points. The 100 adults rated each point as either too sharp, intermediate, or sufficiently dull for use in children's toys under casual handling conditions.

ii. Subjective evaluation by 37 physicians of a similar set of conical points. The physicians rated each point as acceptable or unacceptable for use in children's toys under casual handling conditions.

iii. Actual skin puncture tests performed with the metal points used in the subjective evaluation tests. The skin puncture tests, performed on both human cadaver skin and pigskin samples, were designed to determine what combinations of force and point configuration are necessary to cause punctures that penetrate human skin.

The results from the two groups in the subjective evaluation tests and the results of the skin puncture tests indicated a similar demarcation between sharp and dull points. From these results, NBS developed a sharp point tester capable of judging the sharpness of a point of any shape based on its penetration into a gaging slot of specified width, length, and depth. This tester was included in the sharp point test method proposed on January 7, 1975 by the Commission.

The gaging slot dimensions for the tester found by NBS to best distinguish between points that are sharp and dull to children were a slot with a width of 0.040 inch and a penetration depth allowance of 0.020 inch. The dimension for slot length was based on the NBS conclusion that if two edges of a piece of sheet metal meet at an included angle of 120 degrees or less, a point exists. Using this conclusion and the penetration depth allowance of 0.020 inch, a gaging slot length of 0.070 inch was selected to classify as sharp a 120-degree corner on sheet metal if it has no tip radius.

NBS also incorporated as part of the tester's operation a 0.5 pound spring which a test point must override before an indication is made that the point is sharp. NBS determined that if a point was flexible and could not retain its shape under a force of 0.5 pound than the point would be incapable of puncturing skin.

b. *Articulated probe.* A three-knuckle articulated probe, designed by Underwriters Laboratories (UL) to simulate the penetration of a finger into a small slot or hole, was specified in the proposal on January 7, 1975 for use in determining the accessibility of sharp points to children. A point that is accessible to this probe was determined to be accessible to a child and therefore subject to the sharp point test. The dimensions for the probe were based on the depth of penetration of fingers into slots and holes having respective widths and diameters ranging from 0.125 inch to 1.0 inch. The penetration data wre taken from a study of the finger penetration ability of 100 adult males, 100 adult females, and 100 children. The dimensions used to construct the probe were set so that no more than five percent of the group with the greatest finger penetration (adult females) could reach into the slots and holes to a length greater than that of the probe.

c. *Use and abuse test procedures.* The proposed regulations referenced Commission regulations that prescribe test procedures for simulating the use and abuse of toys and games (16 CFR 1500.50 through 1500.53, published in the FEDERAL REGISTER on January 7, 1975 (40 FR 1480)). These tests are performed in order to simulate the normal use and reasonably foreseeable damage or abuse that is included in the statutory definition of mechanical hazard.

As the regulations were originally proposed, any toy intended for children under 8 years of age would be classified as a hazardous substance and, therefore, a banned hazardous substance if such toy failed to comply with the accessibility and sharp point test method before or after being subjected to the appropriate use and abuse tests.

d. *Skin puncture tests.* i. The Commission received several comments to the

January 7, 1975 proposal which criticized the use of the skin puncture tests NBS performed on human cadaver skin and pigskin samples to establish the test criteria. These tests and other NBS tests described previously have resulted in a determination of what sharpness of metal points is undersirable for use in any toy. The NBS tests are described in NBS report 10739 [2] which may be seen in the Office of the Secretary.

The Commission points out that the NBS skin puncture tests identified as sharp certain conical metal points in a set of 35 such points and that NBS designed a tester that discriminates these conical metal points from points that NBS identified as dull. Such sharp points correlate with the conical metal points that, as described previously, 100 nonphysician adults and 37 physicians determined subjectively to be too sharp for use in children's toys during casual handling. In addition, the Commission has already concluded that points on toys that can puncture or lacerate skin and produce bleeding during normal use or reasonably foreseeable misuse constitute an unreasonable risk of injury. The Commission therefore concludes that there is sufficient research on which to base the technical requirements regulation being proposed below.

ii. Some comments to the January 7, 1975 proposal questioned the technical validity of the skin puncture tests because such tests were conducted on skin samples backed by a rigid plate. The Commission points out that in several places on a child's anatomy (knuckles, forehead, etc.) the resiliency of subdermal tissue is at a minimum and the dermal layer is backed by a rigid bone structure. Therefore, the tests represented certain real-life conditions. In addition, it is difficult to duplicate the resistance to punctures afforded by the resiliency of all of the dermal and subdermal tissue and still maintain the repeatability of the skin puncture tests. The Commission finds no reason to discount the technical validity of the NBS skin puncture research and therefore does not accept the comments.

iii. Additional commentors alleged that the physical properties of skin have not been identified sufficiently to correlate the variations of skin support conditions in both pigskin and human cadaver skin, and that, therefore, the NBS research does not support the test requirements in the sharp point proposal of January 7, 1975.

Based on a NBS literature search of 28 current publications on the subject, the use of skin samples from one preselected area of the skin surface, and medical consultations, the Commission finds that NBS has addressed the various differences between human and animal skin and has established preliminary relationships. Accordingly, the Commission concludes that sufficient studies of skin support conditions have been made to support the type of regulation proposed below.

e. *Force level.* NBS has indicated that during normal use or reasonably foreseeable use of toys, a 5-year-old child can exert a force of at least 16.5 pounds. Many of the commentors questioned NBS's selection of 16.5 pounds as being representative of the force that may be generated by children playing with toys. These commentors believe that this force is greater than the force level that a child could normally exert when playing with toys and twelve commentors believe it is impractical to expect a child to apply 16.5 pounds to a point.

The Commission disagrees with the commentors and points out that the NBS report on the skin puncture potential of points (identified above in footnote 2) indicates that 5-year-old children can exert a force of 16.5 pounds. Further, NBS classified the set of conical points into sharp and dull groups according to tests of the points' skin-puncture potential at 16.5 pounds. NBS noted a strong similarity between the classification of points by their puncture potential at 16.5 pounds and the classification of the same points into sharp and dull groups by the subjective evaluation tests.

Although it is difficult to determine the exact level of force that children will generate when playing with toys, the Commission finds that children at play engage in many activities such as grabbing, holding, crawling, sitting, and rolling that can result in high forces being unintentionally exerted. The Commission therefore finds that the 16.5-pound force used by NBS to define the skin-puncture potential of the conical points is representative of the level of force that can be generated by children playing with toys.

Regarding the criticism that there are inconsistent force levels in the sharp point regulations proposed on January 7, 1975, the use and abuse regulations (16 CFR 1500.50 through 1500.53), and the proposed regulations for sharp edges on toys (16 CFR 1500.18(a)(16) and 1500.47) published in the FEDERAL REGISTER on January 7, 1975 (40 FR 1488), the Commission notes that the proposed sharp edge regulations have not been issued as final regulations and the force level utilized in those regulations may ultimately be changed in response to public comments. Because the merits of that determination should not be addressed in this proceeding, the Commission finds that the comment cannot be further considered at this time.

The Commission finds no inconsistency between the force levels proposed as part of the sharp point test criteria in the regulation below and the maximum levels of force prescribed in the use and abuse regulations because the two are designed to approximate different actions of a child. The sharp point test criteria in the regulation proposed below are derived in part from data related to the gripping strength of young children and the tensile forces specified in the use and abuse regulations are derived from data related to the pulling-strength capabilities of children in designated age groups.

CHANGES TO PROPOSED REGULATION

1. *Test criteria.* In response to public comments and based on continuing staff analysis of the proposal of January 7, 1975, the Commission (a) modified one dimension of the sharp point test instrument, (b) included a test-application force and (c) revised the accessibility criteria by developing two new accessibility test probes. These changes and the reasons supporting them are discussed below in paragraphs 2, 3 and 4.

2. *Sharp point test instrument.* NBS developed a sharp point test instrument that judged the sharpness of a point based on its penetration into a gaging slot of specified width, length, and depth. This tester was included in the sharp point test procedure proposed on January 7, 1975 by the Commission.

As discussed above in paragraph 2—a under the heading "Background," the gaging slot dimensions for the tester found by NBS to best distinguish between points that are sharp and dull to children were a slot with a width of 0.040 inch, a penetration depth allowance of 0.020 inch, and a length of 0.070 inch.

Based on Commission staff recommendations and additional tests conducted on a sample of toys with sharp point test instruments having gaging slots of various lengths, the Commission conclues that a reduction in the length of the gaging slot from 0.070 inch to 0.045 inch is appropriate to identify sharp corners on toys. Such a slot length will identify sharp right-angle corners which have not been rounded-off that the Commission believes present a puncture or laceration hazard. Accordingly, the gaging slot in the sharp point test instrument in the proposed regulation below has been modified to include a rectangular gaging slot measuring 0.040 inch in width, 0.045 inch in length and 0.020 inch in depth.

Detailed engineering drawings for a suggested sharp point tester described in proposed § 1500.48 below are available at a minimum cost from the Office of the Secretary, Consumer Product Safety Commission, 1111 18th Street NW., Washington, D.C. 20207.

3. *Sharp point test-application force.* In response to a commentor's suggestion, the Commission has established a maximum force of 1.0 pound that may be applied to a point when it is inserted into the gaging slot of the tester. The commentor contended and the Commission staff verified, that if excessive force was used when applying a point to the sharp point tester some points with configurations that barely prevent entry into the gaging slot may be shaved or extruded and cause a false indication of sharpness. Section 1500.48(d)(2)(iii) below

[2] "The skin Puncture Potential of Points Associated With Certain Toys," dated April 27, 1972.

now includes the 1.0 pound test-application force.

4. *Accessibility criteria.*—a. *Probes.* In reexamining the research supporting the proposed articulated probe, the Commission finds that the probe, designed by UL, was intended to prevent electric shock where simple contact results in serious injury. UL based the design of the articulated probe on the finger penetration depth of 100 adult males, 100 adult females, and 100 children. The Commission therefore has redrafted the accessibility criteria to simulate only accessibility for children's fingers.

The Commission selected the anthropometric measurements [8] of young children for the lengths and the diameters of the small and middle fingers as well as the dimensions for hand clearance. Because children up to the age of 8 years are in a period of rapid growth, the anthropometric measurements were divided into two age groups—0 to 3 years and over 3 years up to 8 years of age.

To insure protection of the greatest number of children in each age group, the Commission selected anthropometric measurements that reflect the following assumptions:

i. That the younger children in each age group have narrower hands and therefore can reach into openings which would be inaccessible to an older child.

ii. That the older children in each age group have longer fingers and therefore can touch the inside components of toys which would be inaccessible to a younger child.

Furthermore, anthropometric data are not available for the dimensions of a child's index finger. Those dimensions have been approximated by averaging the respective dimensions of the small and middle fingers of children in the two age groups.

In the 0 to 3-year age group, measurements for a fifth-percentile 3-month-old's small and middle fingers were averaged and used to approximate the diameter of the index finger. Measurements for a 95th-percentile 3-year-old's small and middle fingers were averaged and used to approximate the length of the index finger. The minimum hand-clearance measurement of a fifth-percentile 3-month-old child was selected. These measurements were then used to define the dimensions of probe A.

For explanatory purposes, the various percentiles refer to how the size and proportions of one child within a particular age range compare with respect to the size and proportions of other children in the same age range. For example, a fifth-percentile 3-month-old child represents a child of this age, the size of whom is such that 95 percent of the children of the same age are larger and only five percent are smaller.

Similarly for the over 3-year to 8-year age group, measurements for the small and middle fingers of a fifth-percentile child 37–42 months of age were averaged and used to approximate the diameter of the index finger. Measurements for the small and middle fingers of a 95th-percentile child 85–96 months of age were averaged and used to approximate the length of the index finger. The minimum hand-clearance dimensions for a fifth-percentile child 37–42 months of age were selected. These dimensions were then used to define the dimensions of probe B.

Accordingly, probes A and B shown in figure 2 of the regulation below are to be used as follows:

Probe A is to be used to determine the accessibility of points in holes, recesses, or openings on toys intended for children 3 years of age or less.

Probe B is to be used to determine the accessibility of points in holes, recesses, or openings on toys intended for children over 3 years up to 8 years of age.

The Commission notes that the accessibility probes are articulated in two rather than three places, as was the proposed articulated probe, because only two finger joints customarily go through an opening that will not accept the entire hand.

Detailed engineering drawings to enable the construction of the redesigned accessibility probes shown in figure 2 of the regulation below are available at a minimal cost from the Office of the Secretary, Consumer Product Safety Commission, 1111 18th Street NW., Washington, D.C. 20207.

Based on staff recommendations and the anthropometric measurements from the University of Michigan study on the physical characteristics of children (cited in footnote 3, above) for two age groups—0 to 3 years and over 3 years up to 8 years of age, the Commission has defined accessibility for holes, recesses, and openings on toys and other children's articles as follows (holes, recesses, and openings will be referred to hereafter in this paragraph 4 as openings).

b. *Finger access.* Section 1500.48(c)(3)(i) of the proposed regulation provides that access into openings which are large enough to accept a child's finger but too small to accept a child's hand shall be determined by the appropriate accessibility probe shown in figure 2 of the regulation below.

The Commission notes that each of the two joints on the probe may be rotated up to 90 degrees to simulate knuckle movement and that the total depth of insertion for accessibility shall be up to the collar on the probe that is appropriate for either the 0 to 3-year age group (probe A) or the over 3-year to 8-year age group (probe B).

The Commission points out that the diameter of the collar on each probe is representative of the hand-clearance diameter of a fifth percentile child in the youngest age category within each age group. For the 0 to 3-year age group, the youngest age category is 0–3 months of age and for the over 3-year to 8-year age group, the youngest age category is 37–42 months of age.

c. *Hand access but not shoulder access.* Section 1500.48(c)(3)(ii) of the proposed regulation provides that access into openings large enough to accept a child's hand and arm but too small to admit the child's torso (body trunk) shall be determined by the dimensions of the entrance of the opening. Such openings include openings that are larger than the width of a child's hand but smaller than the breadth of a child's shoulders. For the reasons given below, the Commission finds that a depth-of-insertion factor of two and one-quarter multiplied by the minor dimension of an opening is appropriate to determine the accessibility of points in such openings.

The Commission defines a minor dimension of an opening as the diameter of the largest sphere that will pass through the opening. The minor dimension of an opening can be determined by using a pair of calipers. This dimension multiplied by two and one-quarter determines the maxium depth of insertion for accessibility.

The Commission points out that the value of two and one-quarter is the approximate average of the ratio of arm length to shoulder breadth for a 50th percentile child in each of the two age groups—0 to 3 years and over 3 years to 8 years of age. For example, the depth of insertion into an opening with a minor dimension slightly smaller than the breadth of a child's shoulders will be slightly less than the length of the child's arm.

The Commission notes that the detachable extensions of the accessibility (finger) probes shown in figure 2 of the regulation below correlate with the dimensions discussed above and are therefore appropriate for determining the accessibility of points recessed in openings that are larger than the diameter for hand clearance but smaller than the dimension for shoulder breadth. For testing purposes, the appropriate insertion depth should be marked on the probe extension by any suitable means and is the distance from that mark to the tip of the simulated finger. The probe, attached to the probe extension, should be inserted in any direction into the opening up to the depth of the previously made mark. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement and any point that can be contacted by the finger portion of the probe, forward of the probe collar, shall be considered accessible.

d. *Total accessibility.* The Commission has decided that openings larger than the breadth of a child's shoulders shall be considered totally accessible.

For the 0 to 3-year age group, the Commission believes that a shoulder breadth measurement of 7.36 inches is appropriate. This measurement represents a fifth-percentile one-year-old child, since children who are under one-year of age are less mobile and therefore are less likely

[8] All measurements were obtained from the University of Michigan's study, "Physical Characteristics of Children as Related to Death and Injury for Consumer Product Design and Use" (Highway Safety Research Institute, The Unversity of Michigan, Ann Arbor, Mich. 48105).

to climb into cavities than children who are one-year of age or older.

For the over 3-year to 8-year age group, the Commission believes that a shoulder breadth measurement of 9.00 inches is appropriate. This measurement represents a fifth percentile child in the age category of 37–42 months.

The Commission believes that since significant growth occurs within the 0 to 3-year and the over 3-year to 8-year age groups, the measurements of 7.36 and 9.00 inches, respectively, provide an appropriate margin of safety in the tests for accessibility.

The Commission believes that for toys intended for children 0 to 3-years of age, access into openings with a minor dimension (defined above in paragraph 4c) of 7.36 inches or larger shall be considered totally accessible to a child. For toys intended for children over 3 years to 8 years of age, access into openings with a minor dimension of 9.00 inches or larger shall be considered totally accessible to a child. Because openings that are totally accessible to children in the 0–8 years age span may contain smaller openings that are not totally accessible to such children, access into these smaller openings shall be determined by the appropriate procedures explained above in paragraphs 4 b or c.

e. *Inaccessible points.* From the results of sharp point tests conducted on a representative sample of toys, the Commission observes that tabs, wires and other protrusions do not present a puncture or laceration hazard if such protrusions are flush with a protecting surface which is part of the toy. The Commission therefore has decided that a point shall be considered inaccessible if it is protected by an adjacent surface and any gap between the point and the adjacent surface does not exceed 0.020 inch, either before or after application of the appropriate use and abuse test procedures (16 CFR 1500.50 through 1500.53).

Accordingly, the accessibility criteria explained above in this paragraph 4 is included below in proposed § 1500.48(c).

5. *Product-by-product regulatory approach.* The technical requirements regulation concerning toys containing points is proposed under the authority of section 10 of the FHSA as a regulation for the efficient enforcement of the FHSA. Like the use and abuse regulations (16 CFR 1500.50 through 1500.53), the proposed regulation would establish testing criteria but would not itself ban any toy intended for children under 8 years of age. The testing criteria include the sharp point test instrument, the accessibility probes, and the use and abuse tests. If any toy contains points that are identified as sharp, the Commission and its staff will evaluate the toy to determine if it presents a mechanical hazard.

If any such toy does appear to present a mechanical hazard under section 2(s) of the FHSA, the Commission will propose that it be classified as a hazardous substance (and thus a banned hazardous substance) according to sections 2(f)(1)(D), 2(q)(1)(A), and 3(e)(1) of the FHSA (15 U.S.C. 1261, 1262). Interested persons will be notified of the proposal and will have an opportunity to comment to the Commission, in accordance with the Administrative Procedure Act (5 U.S.C. 553). Notification will be by publication of the proposal in the FEDERAL REGISTER or by actual notice to the manufacturer of the affected toy, with notice to the general public, where appropriate. After the Commission and its staff evaluate all comments received, the Commission will issue a final regulation classifying the toy as a hazardous substance (and thus a banned hazardous substance) if the Commission believes that the toy presents a mechanical hazard.

If the Commission decides that a toy containing a point, identified as sharp by the test criteria, does not present a mechanical hazard, the Commission will not initiate regulatory action against that toy.

For example, the Commission notes that certain toys manufactured from soft plastics, such as one some polyethylenes, have molded-in protrusions which indicate a sharp point when tested, but which in reality are too flexible to cause a puncture or laceration injury (e.g., the thin bayonet of certain plastic toy soldiers). The Commission recognizes that the test instrument is not always able to distinguish between soft plastic points that do or do not present a mechanical hazard to children under 8 years of age. However, the Commission is proposing in this document a regulation establishing technical requirements applicable to toys which may contain hazardous sharp points regardless of the material composition of those toys. Since this proposed regulation does not contain automatic banning provisions, the Commission will review those toys which fail the sharp point test criteria on a product-by-product basis. The Commission therefore encourages manufacturers of children's products to make every effort to insure that their product lines comply with the technical requirements because products which fail the test criteria may be subject to additional regulatory action, which may lead to those products being declared banned hazardous substances.

6. *Use and abuse test procedures.* The proposed regulation below would require testing for sharp points before and after application of the appropriate use and abuse test procedures (16 CFR 1500.50 through 1500.53). These test procedures, published as final regulations in the FEDERAL REGISTER of January 7, 1975 (40 FR 1480), do not in and of themselves ban toys and games. Rather, they are for use in exposing potential hazards that result from the normal use or the reasonably foreseeable damage or abuse to which toys and games may be subjected.

The use and abuse test procedures are to be used whenever they are referenced in regulations that are issued pursuant to the FHSA. Such regulations may identify particular mechanical hazards as defined by section 2(s) of the FHSA, which provides, in part, that (a toy) may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury from points.

Bite tests for various age categories are among the Commission's use and abuse test procedures for simulating normal use or reasonably foreseeable damage or abuse. With regard to the bite tests, the Commission finds, based on staff recommendations, that there is some doubt whether children can bite at the force levels specified in each of the bite tests and maintain these forces for the specified ten seconds.

The Commission's research for the bite test procedures and force levels included a study by Dr. Wilton M. Krogman.[4] A copy of the study by Dr. Krogman may be seen in the Office of the Secretary, Consumer Product Safety Commission, 1111 18th Street NW., Washington, D.C., during working hours Monday through Friday.

After reconsidering the Krogman study and the staff's recommendations, the Commission concludes that the bite tests prescribed by §§ 1500.51(c), 1500.52(c), and 1500.53(c) should not be referenced in the proposed regulation below.

EXEMPTIONS

1. *Individual products.* In the case of both bicycles and baby cribs, the Commission notes that these products are covered by comprehensive FHSA regulations that address the hazard of sharp points. Therefore, the Commission proposes to exempt from the technical requirements regulation the bicycles and baby cribs in categories that are addressed in the following three sets of individual product banning regulations:

a. Full-size baby cribs (16 CFR 1500.18(a)(13) and Part 1508) promulgated in the FEDERAL REGISTER of November 21, 1973 (38 FR 32129).

b. Bicycles (16 CFR 1500.18(a)(12) and Part 1512), amended November 13, 1975 (40 FR 52815 and 52828), published in the FEDERAL REGISTER in entirety as amended January 28, 1976 (41 FR 4144) and corrected (printer's error) February 6, 1976 (41 FR 5386).

c. Non-full-size baby cribs (16 CFR 1500.18(a)(14) and Part 1509) promulgated in the FEDERAL REGISTER of February 12, 1976 (41 FR 6238).

2. *Model and craft kits.* An industry association requested that any sharp point regulation exempt model and craft kits because the data, test methods, and other criteria on which the regulation would be based are wholly inapplicable and irrelevant to the essential nature and use patterns of such kits.

The Commission considers adding such an exemption unnecessary because most children under 8 years of age do not have the dexterity and the reading

[4] "Manual and Oral Strengths of American White and Negro Children, Ages 3–6," by Dr. Wilton Krogman (the study by Dr. Krogman, dated September 1, 1971, was sponsored by the Closure Committee of the Glass Container Manufactuers Institute, Inc.).

ability necessary for assembling complicated model and craft kits. The Commission believes also that model and craft kits in the marketplace today are usually not intended for use by children under 8 years of age. Therefore, the Commission finds that such kits are excluded from the scope of the proposed regulation below.

For purposes of the exclusion, the Commission recognizes that model and craft kits are articles containing components which may be unfinished and which require assembly or other necessary processing by the user in order to arrive at a finished product.

3. *Toys and other articles with functional sharp points.* The Commission is proposing to exempt from the technical requirements those toys that have sharp points by reason of their functional purpose, such as needles for toy sewing machines, provided the toy is identified by a conspicuous, legible, and visible label as having sharp points. The Commission is also proposing an exemption for other children's articles that have sharp points by reason of their functional purpose, such as tips on writing instruments. For purposes of both exemptions, non-functional sharp points may not be present on the toy or other article.

PREEMPTION

Section 18(b)(1)(B) of the FHSA, as amended, states:

"Except as provided in paragraphs (2), (3), and (4), if under regulations of the Commission promulgated under or for the enforcement of section 2(q) a requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.

The regulations proposed below are requirements established to protect against the hazard of sharp points on toys intended for children under 8 years of age and they are Commission regulations issued for the enforcement of section 2(q) of the FHSA. Therefore, if the regulations proposed below are issued in final form, the Commission believes and intends that state and local governments would be prohibited from establishing or enforcing any non-identical requirement that addresses the hazard of sharp points on toys intended for children under 8.

The Commission's proposed regulations are "technical requirements" that establish manufacturing criteria for toys intended for children under 8. As long as states or local governments use these same criteria it regulate such toys, their regulations would be considered to be identical to the Commission's regulations. Even if a state or local government were to impose different penalties or use different procedures to regulate toys, there would be no preemption as long as the manufacturing criteria were identical. As an example, if a state were to ban automatically any toy not meeting the criteria, the Commission's position is that such a ban is not preempted by the Commission's technical requirements.

EFFECTIVE DATE

It is contemplated that the effective date will be 365 days from publication of a final regulation establishing technical requirements to identify toys with potentially hazardous sharp points for all products subject to the regulation and introduced into interestate commerce after that date. For purposes of the regulation, introduction into interstate commerce is defined as follows: A toy manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy manufactured in the United States is introduced into interstate commerce (a) at the time of its first interstate sale, or (b) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate.

ENVIRONMENTAL CONSIDERATIONS

An assessment of the potential environmental impact has been made of proposed § 1500.48 establishing technical requirements to identify toys and other articles that are intended for use by children under 8 years of age and that have sharp points presenting a potential puncture or laceration injury hazard. The Commission concludes that there are no potentially significant environmental impacts associated with the proposal. Therefore, there is no need for an environmental impact statement. A copy of the environmental assessment is on file at the Commission and may be inspected at the Office of the Secretary.

METRIC CONVERSION

Throughout the regulation English figures are used. The metric approximations in parentheses are included for convenience and information only.

THE PROPOSAL

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (sec. 2(s), 10(a), 74 Stat. 378 (15 U.S.C. 1261, 1269)) in accordance with the provisions of 5 U.S.C. 553, and under authority vested in the Commission by the Consumer Product Safety Act (Pub. L. 92–573, sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a))), the Commission proposes to amend 16 CFR Part 1500 by adding a new § 1500.48, as follows:

§ 1500.48 Technical requirements for determining a sharp point in toys and other articles intended for use by children under 8 years of age.

(a) *Objective.* The sharp point test prescribed by paragraph (d) of this section will be used by the Commission in making a preliminary determination that points on toys and other articles intended for use by children under 8 years of age, and such points exposed in normal use or as a result of reasonably foreseeable damage or abuse of such toys and articles, present a potential risk of injury by puncture or laceration under section 2(s) of the Federal Hazardous Substances Act (15 U.S.C. 1261(s)). The Commission will further evaluate points that are identified as presenting a potential risk of puncture or laceration injury to determine the need for individual product regulatory action.

(b) *Scope.*—(1) *General.* The sharp point test of paragraph (d) of this section is applicable to toys or other articles that are introduced into interstate commerce on or after (365 days after the publication in the FEDERAL REGISTER of a final regulation). The sharp point test shall be applied to any portion of the test sample before and after subjecting the test sample to the use and abuse tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section).

(2) *Exemptions.* (i) Toys and other children's articles that are the subject of any of the following regulations are exempt from this § 1500.48: The regulations for bicycles, non-full-size baby cribs, and full-size baby cribs (Parts 1508, 1509, and 1512 of this chapter).

(ii) Toys that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this § 1500.48: *Provided,* Each toy is identified, by a conspicuous, legible, and visible label at the time of any sale, as having functional sharp points. An example of such toys is a toy sewing machine with a needle.

(iii) Articles, besides toys, intended for use by children that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this § 1500.48. An example of such articles is a ball-point pen.

(c) *Accessibility.*—(1) *General.* Any point that is accessible either before or after the tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed shall be subject to the sharp point test of paragraph (d) of this section.

(2) *Accessible points.* (i) An accessible point for a toy or article intended for children 3 years of age or less is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe A in figure 2 of this section.

(ii) An accessible point for a toy or article intended for children over 3 years up to 8 years of age is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe B in figure 2 of this section.

(iii) An accessible point for a toy or article intended for children of ages spanning both age groups is one that can be contacted by any portion forward of the collar of either probe A or B, as shown in figure 2 of this section.

(3) *Insertion depth for accessibility.* (i) For any hole, recess, or opening having a minor dimension [5] smaller than the collar diameter of the appropriate probe, the total insertion depth for accessibility shall be up to the collar on the appropriate probe. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(ii) For any hole, recess, or opening having a minor dimension larger than the collar diameter of probe A but less than 7.36 inches (186.9 millimeters), when probe A is used, or a minor dimension larger than the collar diameter of probe B but less than 9.00 inches (228.6 millimeters), when probe B is used, the total insertion depth for accessibility shall be determined by inserting the appropriate probe with the extension shown in figure 2 in any direction up to two and one-quarter times the minor dimension of the hole, recess, or opening, measured from any point in the plane of the opening. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(iii) For any hole, recess, or opening having a minor dimension of 7.36 inches (186.9 millimeters) or larger when probe A is used, or a minor dimension of 9.00 inches (228.6 millimeters) or larger when probe B is used, the total insertion depth for accessibility is unrestricted unless other holes, recesses, or openings within the original hole, recess, or opening are encountered with dimensions specified in paragraph (c) (3) (i) or (ii) of this section. In such instances, the appropriate paragraphs (c) (3) (i) or (ii) of this section shall be followed. If both probes are to be used, a minor dimension that is 7.36 inches (186.9 millimeters) or larger shall determine unrestricted access.

(4) *Inaccessible points.* Points shall be considered inaccessible without testing with a probe if they lie adjacent to a surface of the test sample and any gap between the point and the adjacent surface does not exceed 0.020 inch (0.50 millimeter) either before or after the tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed.

(d) *Sharp point test method*—(1) *Principle of operation.* The principle of operation of the sharp point tester shown in figure 1 of this section is as follows: A rectangular opening measuring a maximum of 0.040 inch (1.02 millimeters) wide by 0.045 inch (1.15 millimeters) long in the end of the slotted cap establishes two reference dimensions. Depth of penetration of the point being tested determines sharpness. If the point being tested can contact a sensing head that is recessed a minimum distance of 0.015 inch (0.38 millimeter) below the end cap and can move the sensing head a further 0.005 inch (0.12 millimeter) against a 0.5-pound (2.2-newton) force of a return spring, the point shall be identified as sharp. A sharp point tester of the general configuration shown in figure 1 of this section or one yielding equivalent results shall identify a sharp point. In conducting tests to determine the presence of sharp points, the Commission will use the sharp point tester shown in figure 1 of this section and the accessibility probes designated as A or B in figure 2 of this section.

(2) *Procedure.* (i) The sample to be tested shall be held in such a manner that it does not move during the test.

(ii) Part of the test sample may need to be removed to allow the sharp point testing device to test a point that is accessible by the criteria of paragraph (c) of this section. Such dismantling of the test sample could affect the rigidity of the point in question. The sharp point test shall be performed with the point supported so that its stiffness approximates but is not greater than the point stiffness in the assembled sample.

(iii) Using the general configuration shown in figure 1 of this section, the adjustment and operation of the sharp point tester is as follows: Hold the sharp point tester and loosen the lock ring by rotating it so that it moves towards the indicator lamp assembly a sufficient distance to expose the calibration reference marks on the barrel. Rotate the gaging cap clockwise until the indicator lamp lights. Rotate the cap counterclockwise until an equivalent of five divisions (the distance between the short lines on the cap) have passed the colibration reference mark. Lock the gaging cap in this position by rotating the lock ring until it fits firmly against the cap. Insert the point into the gaging slot in all directions in which it was accessible by the criteria of paragraph (c) of this section, and apply a force of not more than 1.00 pound (4.45 newtons). A glowing light identifies the point as sharp.

(e) For the purpose of conformance with the technical requirements prescribed by this § 1500.48, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

Interested persons are invited to submit, on or before September 6, 1977, written comments regarding this proposal. Comments and any accompanying data or material should be submitted, preferably in five copies, addressed to the Secretary, Consumer Product Safety Commission, 1111 18th Street, NW., Washington, D.C. 20207. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the Office of the Secretary, at the above address, during working hours Monday through Friday.

Dated: July 29, 1977.

SADYE E. DUNN,
Deputy Secretary,
Consumer Product Safety Commission.

[5] The minor dimension of an opening is the diameter of the largest sphere that will pass through the opening.

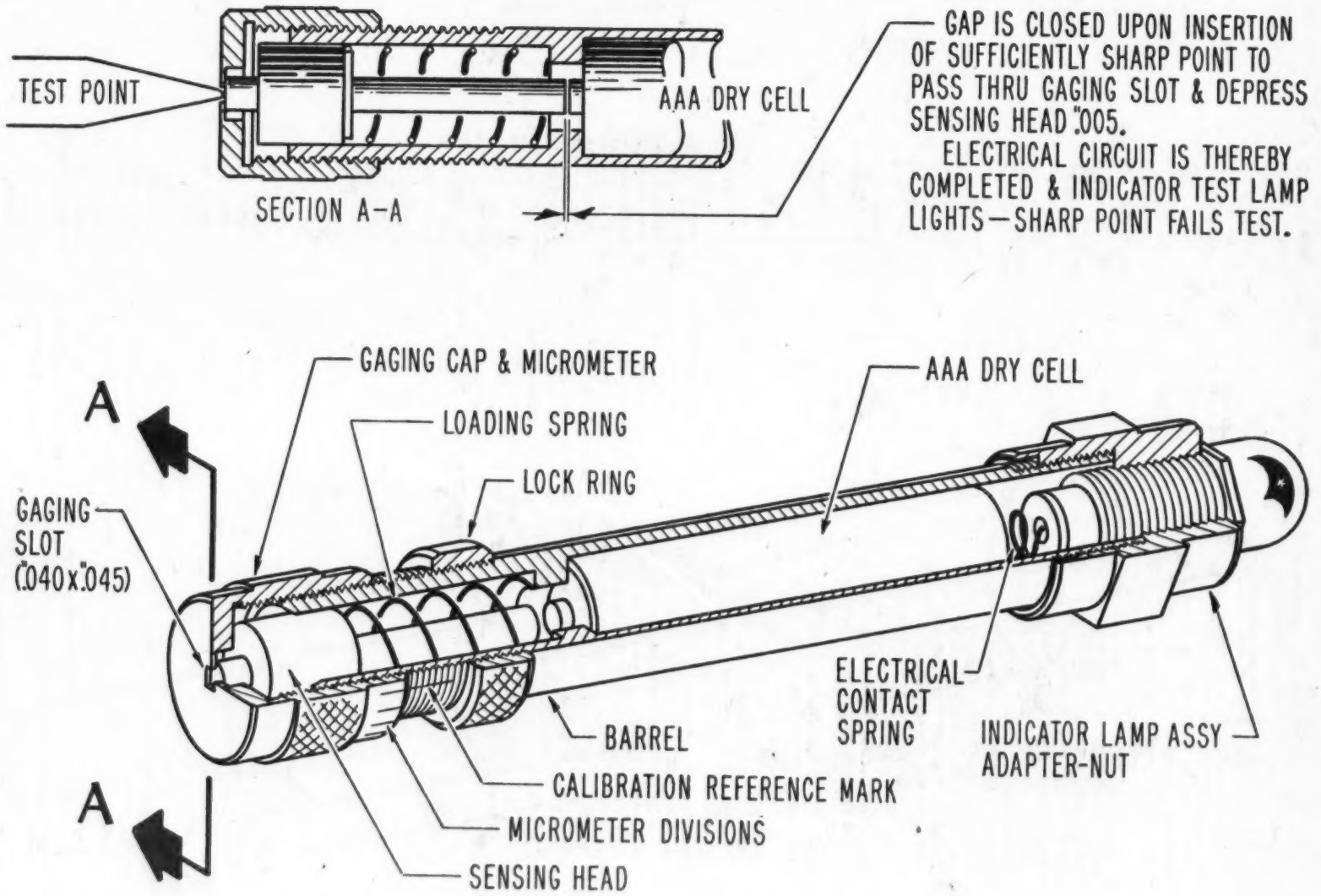
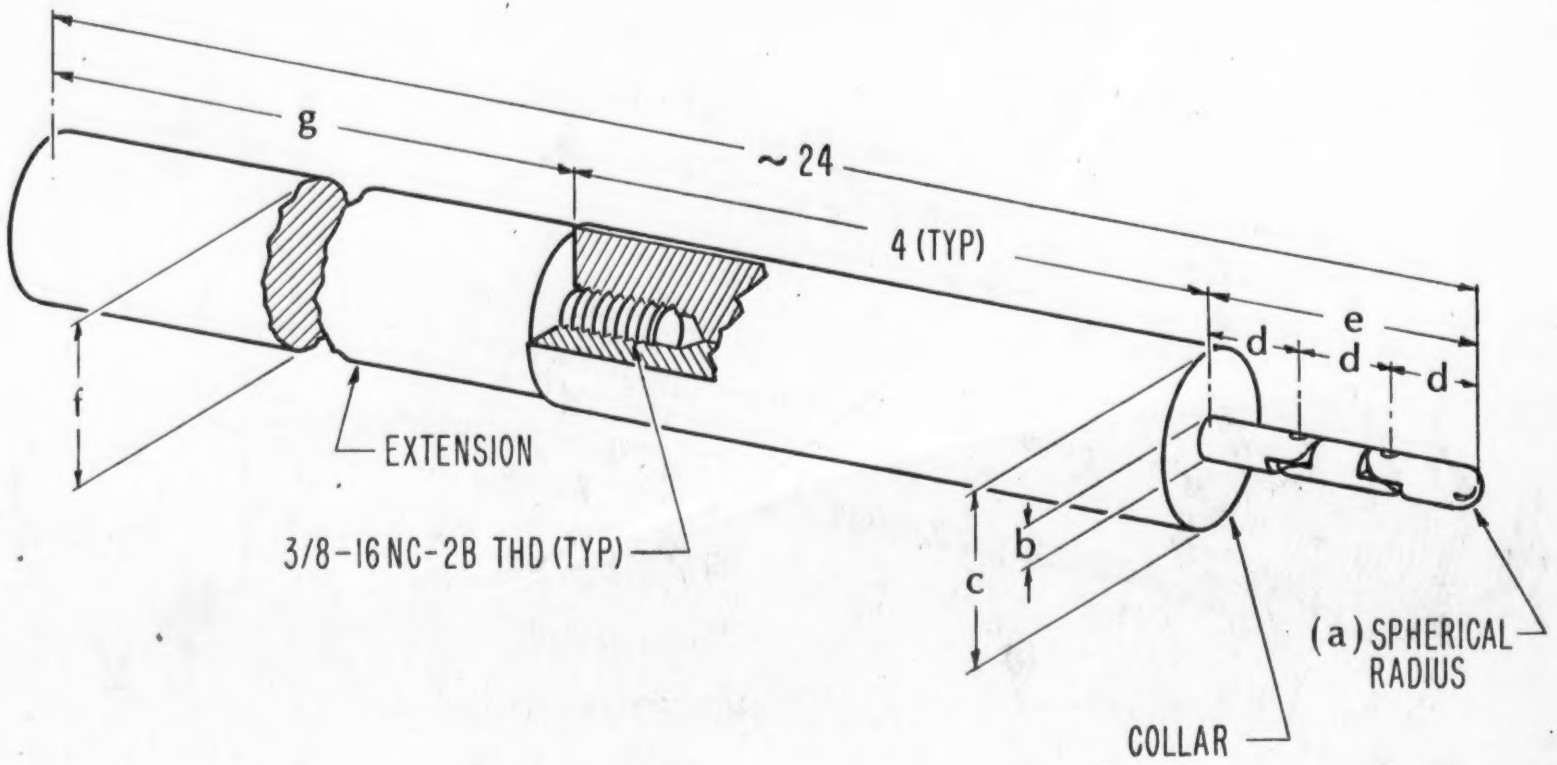

TEST POINT
AAA DRY CELL
SECTION A-A
GAP IS CLOSED UPON INSERTION OF SUFFICIENTLY SHARP POINT TO PASS THRU GAGING SLOT & DEPRESS SENSING HEAD .005.
ELECTRICAL CIRCUIT IS THEREBY COMPLETED & INDICATOR TEST LAMP LIGHTS—SHARP POINT FAILS TEST.
GAGING CAP & MICROMETER
LOADING SPRING
LOCK RING
AAA DRY CELL
A
GAGING SLOT (.040 x .045)
A
ELECTRICAL CONTACT SPRING
INDICATOR LAMP ASSY ADAPTER-NUT
BARREL
CALIBRATION REFERENCE MARK
MICROMETER DIVISIONS
SENSING HEAD

FIG I — SHARP POINT TESTER

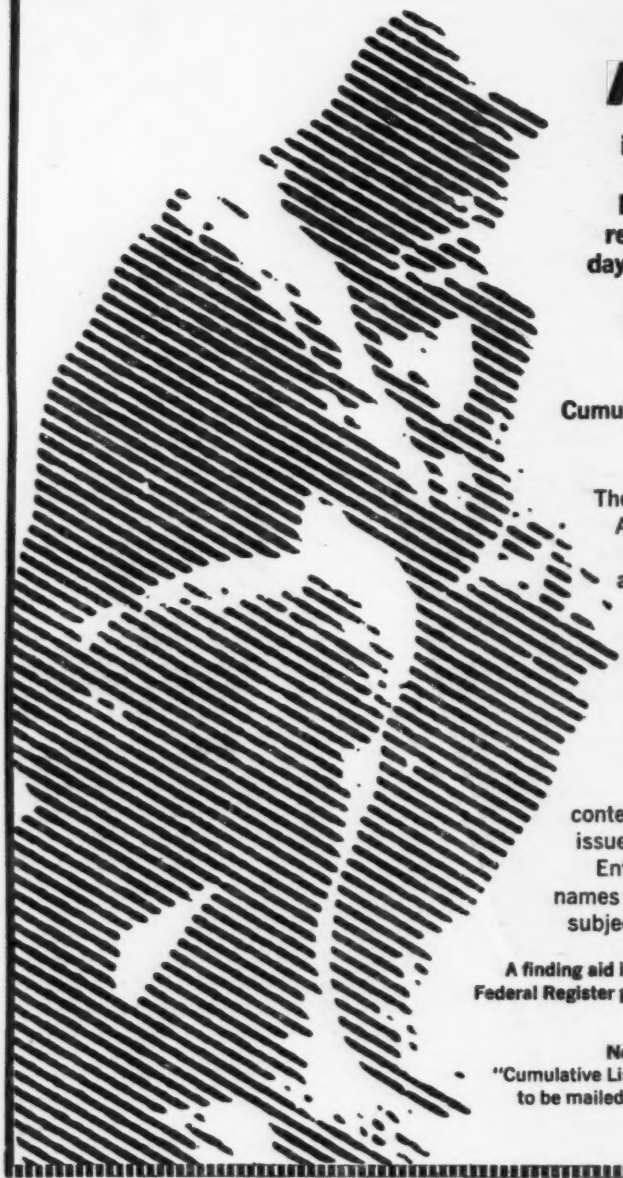


		a	b	c	d	e	f	g
(CHILDREN 0-36 MONTHS INCL)	PROBE A	.110	.220	1.020	.577	1.731	1	18 9/32
(" 37-96 " ")	PROBE B	.170	.340	1.510	.760	2.280	1 1/2	17 25/32

ALL DIMENSIONS IN INCHES

FIG 2—ACCESSIBILITY PROBES

[FR Doc.77-22300 Filed 8-3-77;8:45 am]



would you like to know

if any changes have been made in certain titles of the CODE OF FEDERAL REGULATIONS without reading the Federal Register every day? If so, you may wish to subscribe to the "Cumulative List of CFR Sections Affected," the "Federal Register Index," or both.

Cumulative List of CFR Sections Affected
$10.00
per year

The "Cumulative List of CFR Sections Affected" is designed to lead users of the Code of Federal Regulations to amendatory actions published in the Federal Register, and is issued monthly in cumulative form. Entries indicate the nature of the changes.

Federal Register Index $8.00
per year

Indexes covering the contents of the daily Federal Register are issued monthly, quarterly, and annually. Entries are carried primarily under the names of the issuing agencies. Significant subjects are carried as cross-references.

A finding aid is included in each publication which lists Federal Register page numbers with the date of publication in the Federal Register.

Note to FR Subscribers: FR Indexes and the "Cumulative List of CFR Sections Affected" will continue to be mailed free of charge to regular FR subscribers.

Mail order form to:
Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402

There is enclosed $_____ for _____ subscription(s) to the publications checked below:

..... **CUMULATIVE LIST OF CFR SECTIONS AFFECTED ($10.00 a year domestic; $12.50 foreign)**

..... **FEDERAL REGISTER INDEX ($8.00 a year domestic; $10.00 foreign)**

Name _____

Street Address _____

City _____ **State** _____ **ZIP** _____

Make check payable to the Superintendent of Documents

☆ GPO: 1976—O-56-000